Participant Information for Incarcerated Individuals (objective 1/phase 1)

STUDY TITLE: REASSURED evaluation of the Bioline™ HCV Point-of-care testing for diagnosing HCV infection in primary healthcare settings of Ghana
Supervisor: Prof. Tivani Mashamba-Thompson
Principal Investigators: Evans Duah
Institution: School of Health Systems and Public Health, University of Pretoria, South Africa

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime number/s: +233209067278
Afterhours number: +233209067278

Dear Prospective Participant
Dear Mr. / Mrs. .....

1) INTRODUCTION

You are invited to volunteer for a research study. I am doing research for a PhD Degree purpose at the University of Pretoria, South Africa. The information in this document is to help you to decide if you would like to participate in the current study. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

This study aims to evaluate the Bioline™ HCV Point-of-care testing for diagnosing hepatitis C viral infection in primary healthcare settings of the Central region of Ghana. As part of this, we seek to evaluate the clinical performance (sensitivity and specificity) of the test. By doing so we wish to learn more about the diagnostics of Hepatitis C virus (HCV) disease and to identify a test kit that is more sensitive and specific towards diagnosing HCV infection. HCV is considered a silent epidemic. Late linkage to care may lead to full-blown liver disease and complications such as hepatitis, cirrhosis, and hepatocellular carcinoma. Globally, about 58 million HCV cases have been recorded with 1.5 million new cases annually and 290000 deaths. The HCV seroprevalence in Sub-Saharan Africa stands between 2% and 3% with over 200000 deaths annually. In Ghana, the national HCV prevalence ranges from 1-3%. The infection spreads through blood commonly through sharing of sharp objects and blood transfusion.

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS.

As part of this medical screening being conducted today, we will require that you answer some questions regarding HCV infection. A pre-counseling session will be conducted for you before the start of the study. Similarly, a post-counseling session will be arranged for you after the issuance of your test results.

Duah E, *et al. BMJ Open* 2024; 14:e082416. doi: 10.1136/bmjopen-2023-082416

4) POSSIBLE RISKS AND DISCOMFORTS INVOLVED

There are no medical risks associated with the study. The only possible risk and discomfort involved is the taking of blood from a vein which can result in bruising and bleeding from the puncture site. To identify and link positive cases to medical care, we will require your personal information specifically, your name and ward or prison cell number. We will ensure strict confidentiality.

5) POSSIBLE BENEFITS OF THIS STUDY

You will benefit from this study since it will help you to know your HCV status and if positive, you will be linked to care/ treatment through consultation with the prison warden. If negative, you will be provided with some measures to help you prevent HCV infection. Also, the study results may help us to improve the accessibility, affordability, and performance of the Bioline™ HCV test in Primary Healthcare settings of Ghana.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

7) YOUR RIGHTS AS A RESEARCH PARTICIPANT

We understand that research on the incarcerated population raises ethical concerns due to the confinement of incarcerated individuals and the limitations on their rights. We will respect your rights as a citizen of Ghana and as an inmate as ethics requires. The prison warden is not requiring or forcing you to participate in the study hence you have the free will to refuse to take part in this study or redraw from the study at any point in time without affecting you in any way. Some questions may be sensitive; however, you do not have to answer them if you do not want to. You are assured that there will be no punishment for refusing to participate, redrawing from the study, or refusing to answer some questions. You will only be allowed to participate in this study when you consent to take part. Your information will be kept under strict confidentiality. Only the PI or personnel assigned by the PI may have restricted access to this information.

8) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers (+27) 012 356 3084 / (+27) 012 356 3085, and written approval has been granted by that committee (Ethics reference number: 281/2023). Also, Ethical approval has been granted by the Ghana Health Service Ethics Review Committee (GHS-ERC013/08/23). The study has been structured following the Helsinki Declaration (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research

involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION

If I have any questions concerning this study, I should contact the PI

Evans Duah. Cell: 0209067278

If I have any questions concerning ethics approval, I should contact:

The Ghana Health Service Ethics Review Committee
The ERC Administrator
Nana Abena Apatu
Ghana Health Service
P.O. Box MB 190
Accra
Tel: 0503539896 Email: ethics.research@ghs.gov.gh

10) CONFIDENTIALITY

All information obtained during the course of this study will be regarded as confidential. Each participant that is taking part will be provided with an alphanumeric coded number e.g. A001. This will ensure confidentiality of the information so collected. Only the researcher will be able to identify you as participant. Results will be published or presented in such a fashion that patients remain unidentifiable. The hard copies of all your records will be kept in a locked facility at the School of Health Systems and Public Health, The University of Pretoria.

11) DECLARATION OF CONFLICT OF INTEREST

The researchers declare no conflict of interests

12) FUNDING

The study will be self-funded by Evans Duah with product support from Abbot Diagnostics, Johannesburg, South Africa

Participant Information for patients and blood donors (objective 1/phase 1)

STUDY TITLE: REASSURED evaluation of the Bioline™ HCV Point-of-care testing for diagnosing HCV infection in primary healthcare settings of Ghana
Supervisor: Prof. Tivani Mashamba-Thompson
Principal Investigators: Evans Duah
Institution: School of Health Systems and Public Health, University of Pretoria, South Africa

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime number/s: +233209067278

Afterhours number: +233209067278

Dear Prospective Participant
Dear Mr. / Mrs. .....

1) INTRODUCTION

You are invited to volunteer for a research study. I am doing research for a PhD Degree purpose at the University of Pretoria, South Africa. The information in this document is to help you to decide if you would like to participate in the current study. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to evaluate the Bioline™ HCV Point-of-care testing for diagnosing hepatitis C viral infection in primary healthcare settings of the Central region of Ghana. As part of this, we seek to evaluate the clinical performance (sensitivity and specificity) of the test. By doing so we wish to learn more about the diagnostics of Hepatitis C virus (HCV) disease and to identify a test kit that is more sensitive and specific towards diagnosing HCV infection. HCV is considered a silent epidemic. Late linkage to care may lead to full-blown liver disease and complications such as hepatitis, cirrhosis, and hepatocellular carcinoma. Globally, about 58 million HCV cases have been recorded with 1.5 million new cases annually and 290000 deaths. The HCV seroprevalence in Sub-Saharan Africa stands between 2% and 3% with over 200000 deaths annually. In Ghana, the national HCV prevalence ranges from 1-3%. The infection spreads through blood commonly through sharing of sharp objects and blood transfusion.

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS.

As part of the tests requested by the Doctor or the blood organizer, we will take 4mls of your blood and dispense equally into a gel separator tube and an EDTA tube (2ml each). The sample will be sent to the laboratory and HCV test performed using the Bioline™ HCV Point-of-care test and the ELISA as a confirmatory test. Your results will be communicated to you as soon as possible.

Study duration
The study will be carried out between September 2024 and February 2025. However, it will take about 30 minutes to participate in this study.

4) POSSIBLE RISKS AND DISCOMFORTS INVOLVED

A venous blood sample will be taken which will cause some discomfort and pain in your arm due to the needle prick. However, we have engaged the service of a professional phlebotomist to prevent any adverse effects or outcomes. The phlebotomist will be quick with the sample collection procedure, avoid multiple punctures, apply a tourniquet, and gently massage the arm to mitigate the pain from the venipuncture. Also, the site of the venipuncture will be disinfected with rubbing alcohol to prevent infection at the site of blood collection. Sterile cotton and phlebotomy plasters will be used to prevent infections.

5) POSSIBLE BENEFITS OF THIS STUDY

The study results will help us identify the test or clinical performance of the Bioline™ HCV test using Ghanaian populations. This will help us make recommendations to manufacturers of point-of-care test kits to consider evaluating the test kits using the very populations meant to use them. Also, this will help you know your HCV status.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

7) YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your carreer or profession in any way.

8) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers (+27) 012 356 3084 / (+27) 012 356 3085, and written approval has been granted by that committee (Ethics reference number: 281/2023). Also, Ethical approval has been granted by the Ghana Health Service Ethics Review Committee (GHS-ERC013/08/23). The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION

If I have any questions concerning this study, I should contact the PI

Evans Duah. Cell: 0209067278

If I have any questions concerning ethics approval, I should contact:

The Ghana Health Service Ethics Review Committee
The ERC Administrator
Nana Abena Apatu
Ghana Health Service
P.O. Box MB 190
Accra
Tel: 0503539896 Email: ethics.research@ghs.gov.gh

10) CONFIDENTIALITY

All information obtained during the course of this study will be regarded as confidential. Each participant that is taking part will be provided with an alphanumeric coded number e.g. A001. This will ensure confidentiality of the information so collected. Only the researcher will be able to identify you as participant. Results will be published or presented in such a fashion that patients remain unidentifiable. The hard copies of all your records will be kept in a locked facility at the School of Health Systems and Public Health, The University of Pretoria.

11) DECLARATION OF CONFLICT OF INTEREST

The researchers declare no conflict of interests

12) FUNDING

The study will be self-funded by Evans Duah with product support from Abbot Diagnostics, Johannesburg, South Africa

Participant Information for health staff (objective 2/phase 2)

STUDY TITLE: REASSURED evaluation of the Bioline™ HCV Point-of-care testing for diagnosing HCV infection in primary healthcare settings of Ghana
Supervisor: Prof. Tivani Mashamba-Thompson
Principal Investigators: Evans Duah
Institution: School of Health Systems and Public Health, University of Pretoria, South Africa

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime number/s: +233209067278
Afterhours number: +233209067278

Dear Prospective Participant
Dear Mr. / Mrs. .....

1) INTRODUCTION

You are invited to volunteer for a research study. I am doing research for a PhD Degree purpose at the University of Pretoria, South Africa. The information in this document is to help you to decide if you would like to participate in the current study. Before you agree to take part in this study you

should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to evaluate the Bioline™ HCV Point-of-care testing for diagnosing hepatitis C viral infection in primary health care settings of the Central region of Ghana. As part of this, we seek to understand your perceptions as you use the Bioline™ HCV test presented to you. By doing so we wish to learn more about the diagnostics of Hepatitis C virus (HCV) disease. HCV infection is a viral infection that is increasingly affecting populations in the world. Late linkage to care may lead to full-blown liver disease and complications such as hepatitis, cirrhosis, and hepatocellular carcinoma. Globally, about 58 million HCV cases have been recorded with 1.5 million new cases annually and 290000 deaths. The HCV seroprevalence in Sub-Saharan Africa stands between 2% and 3% with over 200000 deaths annually. In Ghana, the national HCV prevalence ranges from 1-3%. The infection spreads through blood commonly through sharing of sharp objects and blood transfusion. Existing literature identifies incarcerated individuals as a vulnerable group to Hepatitis C virus (HCV) infection largely among people who share sharp objects (e.g. Razor blades and needles), people with tattoos, people who use or inject drugs, and men who have sex with men (MSM).

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS.

This study involves receiving some training on how to use the Bioline™ HCV test for diagnosing HCV in your facility. You will also be observed by a research assistant whilst using the Bioline™ HCV test. This will be followed by answering some questions about your experience and perceptions about the use of the Bioline™ HCV test through interviews and paper questionnaires. The interview session will be recorded on tape.

Study duration
The study will be carried out between September 2024 and February 2025. However, it will take about 30 minutes to participate in this study.

4) POSSIBLE RISKS AND DISCOMFORTS INVOLVED

As part of the evaluation of the test, you will be required to perform the test whilst the researchers observe. This will require that you prick the finger of your paired colleague whilst he or she does the same to you. You may feel a little pain at the site of prick. A regulated lancet holder will be used to mitigate the pain you may feel.

5) POSSIBLE BENEFITS OF THIS STUDY

Duah E, *et al. BMJ Open* 2024; 14:e082416. doi: 10.1136/bmjopen-2023-082416

The study results may help us to improve the accessibility, affordability, and performance of the Bioline™ HCV test in Primary Healthcare settings of Ghana. Similarly, you may benefit from the availability and use of an evaluated test that meets your expectations and helps to diagnose HCV at POC. Also, this will help you know your HCV status.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

7) YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your career or profession in any way.

8) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers (+27) 012 356 3084 / (+27) 012 356 3085, and written approval has been granted by that committee **(Ethics reference number: 281/2023).** Also, Ethical approval has been granted by the Ghana Health Service Ethics Review Committee (GHS-ERC013/08/23). The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION

If I have any questions concerning this study, I should contact the PI

Evans Duah. Cell: 0209067278

If I have any questions concerning ethics approval, I should contact:

The Ghana Health Service Ethics Review Committee
The ERC Administrator
Nana Abena Apatu
Ghana Health Service
P.O. Box MB 190
Accra
Tel: 0503539896 Email: ethics.research@ghs.gov.gh

10) CONFIDENTIALITY

Duah E, *et al. BMJ Open* 2024; 14:e082416. doi: 10.1136/bmjopen-2023-082416

All information obtained during the course of this study will be regarded as confidential. Each participant that is taking part will be provided with an alphanumeric coded number e.g. A001. This will ensure confidentiality of the information so collected. Only the researcher will be able to identify you as participant. Results will be published or presented in such a fashion that patients remain unidentifiable. The hard copies of all your records will be kept in a locked facility at the School of Health Systems and Public Health, The University of Pretoria.

11)DECLARATION OF CONFLICT OF INTEREST
The researchers declare no conflict of interests

12)FUNDING
The study will be self-funded by Evans Duah with product support from Abbot Diagnostics, Johannesburg, South Africa

Participant Information for health staff (objective 3/phase 3)

STUDY TITLE: REASSURED evaluation of the Bioline™ HCV Point-of-care testing for diagnosing HCV infection in primary healthcare settings of Ghana
Supervisor: Prof. Tivani Mashamba-Thompson
Principal Investigators: Evans Duah
Institution: School of Health Systems and Public Health, University of Pretoria, South Africa

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime number/s: +233209067278
Afterhours number: +233209067278

Dear Prospective Participant
Dear Mr. / Mrs. .....
1) INTRODUCTION

You are invited to volunteer for a research study. I am doing research for a PhD Degree purpose at the University of Pretoria, South Africa. The information in this document is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to evaluate the Bioline™ HCV Point-of-care testing for diagnosing hepatitis C viral infection in primary health care settings of the Central region of Ghana. As part of this, we seek to compare the cost composition of the available HCV test in your facility and that of using the Bioline™ HCV test. HCV infection is a viral infection that is increasingly affecting populations in the world. Late linkage to care may lead to full-blown liver disease and complications such as

hepatitis, cirrhosis, and hepatocellular carcinoma. Globally, about 58 million HCV cases have been recorded with 1.5 million new cases annually and 290000 deaths. The HCV seroprevalence in Sub-Saharan Africa stands between 2% and 3% with over 200000 deaths annually. In Ghana, the national HCV prevalence ranges from 1-3%. The infection spreads through blood commonly through sharing of sharp objects and blood transfusion. Existing literature identifies incarcerated individuals as a vulnerable group to Hepatitis C virus (HCV) infection largely among people who share sharp objects (e.g. Razor blades and needles), people with tattoos, people who use or inject drugs, and men who have sex with men (MSM).

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS.

This study involves answering some questions about the cost implications and compositions of the current test algorithms available in your facility for testing HCV. For example: how much it cost a patient to perform HCV test in your facility.

Study duration
The study will be carried out between September 2024 and February 2025. However, it will take about 30 minutes to participate in this study.

4) POSSIBLE RISKS AND DISCOMFORTS INVOLVED

There are no medical risks associated with the study.

5) POSSIBLE BENEFITS OF THIS STUDY

The study results may help us to improve the accessibility, affordability, and performance of the Bioline™ HCV test in Primary Healthcare settings of Ghana. Similarly, you may benefit from the availability and use of an evaluated test that meets your expectations and helps to diagnose HCV at POC.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

7) YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason.

8) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers (+27) 012 356 3084 / (+27) 012 356 3085, and written approval has been granted by that committee (Ethics reference number: 281/2023). Also, Ethical approval has been granted by the Ghana Health Service Ethics Review Committee (GHS-ERC013/08/23). The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION

If I have any questions concerning this study, I should contact the PI

Evans Duah. Cell: 0209067278

If I have any questions concerning ethics approval, I should contact:

The Ghana Health Service Ethics Review Committee
The ERC Administrator
Nana Abena Apatu
Ghana Health Service
P.O. Box MB 190
Accra
Tel: 0503539896 Email: ethics.research@ghs.gov.gh

10) CONFIDENTIALITY

All information obtained during the course of this study will be regarded as confidential. Each participant that is taking part will be provided with an alphanumeric coded number e.g. A001. This will ensure confidentiality of information so collected. Only the researcher will be able to identify you as participant. Results will be published or presented in such a fashion that patients remain unidentifiable. The hard copies of all your records will be kept in a locked facility at the School of Health Systems and Public Health, The University of Pretoria.

11)DECLARATION OF CONFLICT OF INTEREST

The researchers declare no conflict of interests

12)FUNDING

The study will be self-funded by Evans Duah with product support from Abbot Diagnostics, Johannesburg, South Africa